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I, ANNA MAIJA EVERETT, ACTING TEAM LEADER EXAMINATION SUPPORT & SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ 0365 for a patent by FAIRMONT MEDICAL PRODUCTS PTY LTD filed on 14 May 1999.



WITNESS my hand this  
Twenty-sixth day of May 2000

*A. M. Everett.*

ANNA MAIJA EVERETT  
ACTING TEAM LEADER  
EXAMINATION SUPPORT & SALES

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**PROVISIONAL SPECIFICATION**

**FOR THE INVENTION ENTITLED:**

**"STERILISATION METHOD AND CONTAINER THEREFOR"**

**Applicant:**

**FAIRMONT MEDICAL PRODUCTS PTY LTD**

The invention is described in the following statement:

## STERILIZATION METHOD AND CONTAINER THEREFOR

The present invention relates to a container for use in sterilizing an object and to a method for sterilizing an object. The apparatus and method of the present invention are particularly suitable for use in sterilizing medical and surgical equipment.

Surgical operations must be carried out under strict conditions of sterility to minimize infection risk in the patient. To this end, a sterile field is set up in the operating theatre around the patient. Any theatre staff, such as surgeons or nurses, who have to touch the patient during surgery must rigorously scrub and wear sterile surgical gloves. All instruments and equipment used in the surgery must also be sterile.

Surgical equipment is frequently supplied inside sterile packaging which ensures that the equipment inside the packaging is sterile and remains so whilst the packaging remains unopened. However, storage, handling and distribution of the packaging causes the outer surface of the packaging to become non-sterile. To account for this whilst maintaining the sterile field in the operating theatre, surgical teams include a non-sterile nurse who opens the packaging of pieces of surgical equipment and exposes the sterile equipment to a nurse within the sterile field. The nurse within the sterile field then removes the sterile equipment from the packaging. Provided that the non-sterile nurse does not touch the equipment, sterility of the sterile field is not compromised.

A number of pieces of medical and surgical equipment are re-usable. In order to re-use such equipment, it is necessary to sterilize the equipment before use in the next operation. Sterilization of medical and surgical equipment is commonly carried out in an autoclave in which steam at elevated pressure and a temperature in excess of 100°C sterilizes the equipment.

Although autoclaving is an effective sterilizing method, difficulties can arise when it is desired to sterilize delicate medical and surgical equipment. In particular a number of pieces of equipment are typically loaded into the autoclave at a time,, which can lead to breakage of delicate equipment. Moreover, it can be difficult to

maintain sterility of the equipment when it is removed from the autoclave and stored for use in the next operation.

Other methods of sterilisation that are frequently used include exposing the medical apparatus to a sterilising gas, such as ethylene oxide, or soaking in a  
5 sterilising liquid.

Endoscopic or laparoscopic surgery, also commonly known as key-hole surgery, is become more wide spread. Endoscopic and laparoscopic techniques are low invasive techniques that can dramatically reduce the duration of stays in hospitals by patients. Endoscopic and laparoscopic techniques require the use of telescopes  
10 (hereinafter called "endoscopic telescopes" for convenience) to enable the surgeon to see the site of the surgery on a monitor. Endoscopic telescopes comprise an elongated body in the form of a thin tube having an enlarged housing at one end thereof, which housing contains optical components and allows coupling to a camera or video feed. The other end of the endoscopic telescope is inserted into the patient via an incision  
15 made in the patient's skin. The endoscopic telescope projects into the sterile field and hence the endoscopic telescope must be sterilized.

It is an object of the present invention to provide a method for and an apparatus for use in sterilizing an object such as a piece of medical or surgical equipment.

In one aspect, the present invention provides a method for sterilizing an object  
20 including placing the object into a container, the container having an opening through which the object is inserted, closing the opening with a vapour permeable closure and placing the container in a sterilizing environment for sufficient time to sterilize the object.

Preferably, the vapour permeable membrane is a water vapour permeable  
25 membrane.

Preferably, the vapour permeable membrane is also permeable to liquid water.

Preferably the step of placing the container in a sterilizing environment includes the step of placing the container in an autoclave and operating the autoclave for sufficient time to sterilize the object. Although autoclaving is the preferred  
30 sterilizing method, other sterilizing methods may be used. Such methods may include

placing the container in a sterilizing fluid. In such cases, the closure should also be permeable to the sterilizing fluid.

The step of closing the opening of the container preferably includes the step of affixing a vapour-permeable closure to a rim of the opening. The closure may be  
5 affixed to the rim of the opening by an adhesive. The closure may comprise any suitable vapour permeable material. Preferably, the material is also permeable to other fluids, such as gases. However, it is preferred that the closure material does not allow the passage of bacteria therethrough.

The closure material may comprise a microporous membrane. More  
10 preferably, the closure material comprises a paper or paper-based material. It will be appreciated that the closure material should be resistant to failure under the sterilizing conditions used. For example, a thermoplastic material that melts at a temperature below the temperature used in an autoclave is unsuitable for use in the present invention if autoclaving is to be used to obtain sterilization.

15 By placing the object in a container and closing the opening in the container, the object is protected from damage by contact with other objects during sterilization by virtue of the object being protected by the container. The closure confines the object within the container and prevents the entry of bacteria into the container after sterilization is complete. Thus, the container also provides a convenient storage  
20 container that can maintain sterility of the object.

In another aspect of the present invention provides a container for use in sterilizing an object, the container adapted to receive the object, the container including an open end to allow insertion of the object into the inner volume, a second end located generally opposite the open end and wherein at least a portion of the  
25 container is adapted to be collapsed or deformed whereby the open end and the second end are moved relatively towards each other.

Preferably, at least a portion of the container near the open end is collapsible or deformable whereby collapsing or deforming of the collapsible or deformable portion causes the open end to move relatively closer to the closed end.

30 Preferably, the container includes an elongate portion for receiving an elongate object.

Preferably, the container is relatively enlarged at the open end. This allows easier insertion of the object into the container. It also enables the container to hold objects having a relatively enlarged part, for example, such as an endoscopic telescope. Preferably, the container is adapted to contain a piece of medical or surgical equipment, more preferably an elongated medical apparatus, most preferably an endoscopic telescopic.

Preferably, the open end of the container is sealable by a vapour-permeable closure. The vapour-permeable closure may be affixed to the rim of the open end to thereby close the open end. The vapour permeable closure may be removed from the open end by peeling. The vapour permeable closure may comprise a paper or paper-based material or a microporous material.

The vapour permeable membrane is preferably a water vapour permeable membrane. The vapour permeable membrane is preferably permeable to liquid water.

In another embodiment, the open end of the container may be closed after insertion of the object to be sterilized has been inserted therein by placing a lid or cap on the open end, which lid or cap includes a vapour-permeable portion. Preferably, the lid or cap is a screw-on lid or cap that has a threaded portion that co-operates with a complementary threaded portion formed on the container. Alternatively, the lid or cap may be a pop-on type.

The lid or cap is preferably provided with a tamper-proof seal or a tamper evident seal.

The lid or cap may be provided with a vapour-permeable portion by forming the lid or cap with an opening and covering the opening with a vapour-permeable material. The vapour permeable material may comprise a paper or paper-based material or a microporous material. Alternatively, the lid or cap may be manufactured from a vapour-permeable material.

The second end of the container may be formed as a closed end. More preferably, the second end of the container is closed by a vapour permeable means. This allows air to circulate through the container after autoclaving to thereby assist in drying any condensed water inside the container. The vapour permeable means may be a paper or paper-based closure means or a microporous material. In embodiments

where the second end is a closed end and is formed from the material of the container, one or more vapour-permeable windows may be provided in the container. Indeed, one or more vapour-permeable windows may be provided even if the second end has a vapour-permeable closure thereon.

5       A part of the container may be provided with indicating means to indicate whether or not the container has been exposed to a sterilising environment. The indicating means may be a colour change portion that undergoes a colour change when exposed to the sterilising environment. The colour change may be caused by exposure to elevated temperature or the sterilising gas. Preferably, the indicating  
10       means forms part of the vapour permeable closure.

      The container of the present invention provides a container for containing a piece of medical or surgical equipment during sterilization. The container protects the medical or surgical equipment from damage during sterilization. By closing the open end of the container with the vapour permeable closure, sterilization of the medical or  
15       surgical equipment can be achieved and the medical or surgical equipment can be stored in sterile conditions inside the container following sterilization. The container may include indication means to indicate if the container has been sterilised. The indicator means is preferably a replaceable vapour permeable closure.

      Moreover, the provision of a collapsible or deformable portion allows the  
20       equipment inside the container to be easily accessed during a surgical operation. In particular, in use in a surgical operation, the non-sterile nurse removes the closure and then collapses or deforms the collapsible or deformable portion of the container. Consequently, the sterile piece of medical or surgical equipment inside the container is at least partially exposed and the sterile nurse can grasp the exposed part and remove  
25       the sterile equipment from the container. The container of the present invention allows the sterilized equipment to be removed therefrom without the non-sterile nurse having to touch the sterile inner part of the container and the sterile equipment inside the container. The sterile nurse does not have to touch the non-sterile outer surface of the container.

30       The collapsible or deformable portion of the container is preferably made to collapse or deform in a concertina fashion. To this end, the collapsible or deformable

portion may include a plurality of fold lines or lines of weakness extending around the container. It will be appreciated that the present invention also includes any other collapsible or deformable portion. For example, the container may include a portion made from a pliant material or include a portion able to be folded back upon itself, or  
5 include a corrugated or fluted portion.

The container may be made from any material that is resistant to the conditions encountered in sterilization. The container is preferably made from suitable plastics material. Polyethylene is particularly preferred. The container may be made in one piece or it may be made from two or more pieces joined together. Containers of  
10 varying size may be made to accommodate telescopes or other instruments of varying size. The inside surface of the container is preferably hydrophobic or treated to be hydrophobic. The container may also be gamma-ray permeable to leave open the possibility of using in gamma-ray sterilisation.

A preferred embodiment of the present invention will now be described with  
15 reference to the accompanying drawings in which:

Figure 1 shows a perspective side view of a container in accordance with the present invention;

Figure 2 shows a cross-sectional side view of the container of Figure 1 with an endoscopic telescope positioned within the container;

20 Figure 3 shows a cross-sectional side view of the apparatus of Figure 2 but showing how the endoscopic telescope is removed from the container;

Figure 4 shows an end view of one embodiment of a container in accordance with the present invention;

Figure 5 shows a modification of the container of Figure 1 having pull rings to  
25 simplify collapse of the container; and

Figure 6 shows a container in accordance with another embodiment of the present invention.

The embodiment of the present invention shown in the attached figures is particularly useful in the sterilization of medical or surgical equipment by autoclaving  
30 and for convenience the embodiment of the invention will be described with reference to autoclaving. However, it is to be understood that the present invention is equally



applicable to use in other sterilization methods besides autoclaving and that the invention should not be considered to be limited solely to autoclaving. Furthermore, the embodiment shown in the attached figures relate to the sterilization of an endoscopic telescope. Again, it will be appreciated that medical or surgical equipment  
5 other than endoscopic telescopes may be sterilized in accordance with the present invention and that it is not intended that the present invention be restricted to the sterilization of endoscopic telescopes.

Turning now to consider Figure 1, a container 1 in accordance with the present invention includes an elongate tubular portion 2, and an enlarged portion 3 at the  
10 proximal end of the container. The enlarged portion 3 includes an open end 4 defined by a rim 5. The container also includes a second, closed end 6 that is located generally opposite the open end 4. The enlarged portion 3 includes a series of fold lines or lines of weakness 7, indicated in dashed outline. The fold lines or lines of weakness 7 allow the enlarged portion 3 to be collapsed upon itself in concertina like fashion, as  
15 best shown in Figure 3.

Turning now to consider Figure 2, which shows a cross-sectional view of the container of Figure 1 as filled with an endoscopic telescope, the container 1 of Figure 2 is shaped to receive an endoscopic telescope 8. The endoscopic telescope 8 includes an elongate portion 9 that extends into the elongate portion 2 of container 1. The  
20 endoscopic telescope 8 also includes a proximal end 10 that includes a housing 11 for housing optical components and a clamping means 12. As can be clearly seen from Figure 2, the enlarged end 10 of the endoscopic telescope 8 fits inside the enlarged portion 3 of container 1. To assist in inserting the elongate portion 9 of endoscopic telescope 8 into the elongate portion 2 of endoscopic telescope 1, a tapered guide 13 is  
25 fitted to the elongate part 2 of the container 1. The elongate part 2 of container 1 is also fitted with sponge holder 13 and sponge padding 14 to provide support for the end of the endoscopic telescope.

After the endoscopic telescope 8 is inserted through the opening 4 in container 1, vapour permeable closure 15 is affixed to the opening to thereby close the opening  
30 4. In the embodiment shown in the figures, the vapour permeable closure 15 comprises a paper or paper base material that is affixed to the container by adhesive 16

that contacts the rim 5 of the opening 4. Although Figure 2 shows the water vapour permeable closure 15 extending beyond the edges of the container, it will be appreciated that the vapour permeable closure 15 may sit flush with the edges of the container. The vapour permeable closure is preferably water vapour permeable and is also preferably permeable to liquid water.

In order to sterilize the endoscopic telescope, the container 1 having the endoscopic telescope 8 placed therein and vapour permeable closure 15 affixed thereto is placed inside an autoclave. Operation of the autoclave causes steam and possibly water to pass through vapour permeable closure 15 and into the inner volume of container 1. This results in sterilization of the endoscopic telescope. At the end of the autoclave cycle, the autoclave is turned off and is depressurised. Any water that has condensed inside container 1 can run out of the container and permeate through permeable closure 15. This leaves the inside of the container 1 substantially dry. In this regard, it will be noted that although lines of weakness or fold lines 7 are formed in the enlarged portion of the container 1, in the uncollapsed state shown in Figures 1 and 2, the inside of the enlarged portion 3 of container 1 presents a substantially smooth surface that does not collect any condensed water.

Once the container shown in Figure 2 is removed from the autoclave, it may be stored for future use. The inside of the container remains sterile because permeable closure 15 prevents the entry of bacteria into the container. Moreover, the container 1 provides protection for the endoscopic telescope 8 against bumps and rough handling.

When it is time to use the endoscopic telescope 8 in a surgical procedure, the container 1 containing endoscopic telescope 8 is transferred to the operating theatre. In the operating theatre, a non-sterile nurse picks up the container 1 and collapses or deforms the enlarged portion 3 by pulling the enlarged portion 3 towards the closed end 6. It will be appreciated that the permeable closure 15 is either removed prior to deforming the enlarged portion 3 or is removed by the act of deforming the enlarged portion 3. As best shown in Figure 3, deforming the enlarged portion 3 by urging it towards the second, closed end 6 causes the open end 4 to move relatively towards the second, closed end 6. The enlarged portion 3 collapses or deforms in a concertina like manner around fold lines or lines of weakness 7. This has the effect of exposing

enlarged end 10 of endoscopic telescope 8 from the open end 4 of container 1. A sterile nurse can then grasp the end 10 of endoscopic telescope 8 and withdraw the endoscopic telescope 8 from the container 1. As the end 10 of endoscopic telescope 8 is sterile, the sterile nurse does not compromise the sterile field in the operating theatre by this operation.

Once the endoscopic container 8 has been removed from the container 1, the container may either be washed ready for resterilization or simply discarded.

The container 1 may have any suitable profile. In one embodiment, best shown in Figure 4, the enlarged portion 3 of container 1 has a generally square or rectangular profile, with the rim 5 of open end 4 defining that particular profile. The advantage of the profile shown in Figure 4 is that the container 1 is then stackable on other similar containers for ease of storage. However, it will be appreciated that any other profile for the container may be used.

In order to improve the operation of collapsing the enlarged portion 3 of the container 1, as best shown with reference to Figure 3, the enlarged portion 3 of container 1 may be provided with ring pulls 17, 18 for grasping by the non-sterile nurse. This is best shown in Figure 5. Alternatively, pull tabs may be provided.

The container 1 shown in the embodiment of the present invention may be integrally formed as a single unit. Alternatively, the container 1 may be formed from two or more parts that are joined together. For example, the elongate portion 2 of container 1 may comprise an extruded tube. Closed end 6 may be attached to one end of the extruded tube, for example, by ultrasonic welding or by use of a suitable water tight adhesive. Similarly, enlarged portion 3 may be attached to the other end of extruded portion 2, again by ultrasonic welding or by use of a suitable adhesive.

Turning now to figure 6, the container 20 comprises an elongated barrel 21 and an enlarged end portion 22. Enlarged end portion 22 has an open end that is adapted to be closed by screw cap 23. Screw cap 23 has a peel paper seal 24 adhered thereto. The peel paper seal 24 closes an opening in screw cap 23. Although not shown in figure 6, screw cap 23 screws on to a threaded portion formed on the end of container 20. The screw cap 23 is also provided with a tamper proof or tamper evident seal 25. This seal may be similar to those found on bottles of fruit juice. The tamper proof or

tamper evident seal provides a further level of security to the medical staff that the contents of the container are sterile and have not been opened following sterilisation.

5 The peel paper seal also may include a colour change portion that changes colour, preferably irreversibly, under sterilising conditions. This portion gives an indication to the medical staff as to whether the contents of the container have been sterilised.

The enlarged end portion 22 also includes finger indentations 26, 27 that are designed to assist in grasping and using the container.

10 The second end 28 of the container has an opening formed therein and a paper seal 29 is applied over that opening. The paper seal 29 allows air to permeate therethrough and this then permits drying of any water that may have condensed inside the container during sterilization.

15 The container 20 shown in figure 6 is also provided with corrugations 30 that allow the pull back exposure of the telescope. Corrugations 30 are provided in the barrel of the container. In particular, the container can be collapsed by moving the ends of the container towards each other, which thereby causes the corrugations to collapse upon themselves.

20 The container 20 shown in figure 6 is preferably made from polyethylene, which is a heat resistant plastic. However, any other heat resistant material may be used as the material of construction for the container. The screw cap 23 may be made of nylon or polycarbonate to enhance adhesion of the peel paper seal 24 to the screw cap. The peel paper seal applied to the screw cap may have printing thereon to advise users of the contents of the container and also to include information such as the date the contents were sterilized, the sterilizing conditions and the operator who performed the  
25 sterilization procedure.

30 The container of the present invention may be made in a number of different lengths to suit different types of telescopes for sterilization. It will also be appreciated that although figures 1 to 6 show the invention used in conjunction with the sterilization of endoscopic telescopes, the invention may be extended to cover the sterilization of a number of different types of medical apparatus.

It will be appreciated that the invention described herein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention encompasses all such variations and modifications that fall within its spirit and scope.

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DATED: 14 May 1999

**CARTER SMITH & BEADLE**

Patent Attorneys for the Applicant:

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**FAIRMONT MEDICAL PRODUCTS PTY LTD**

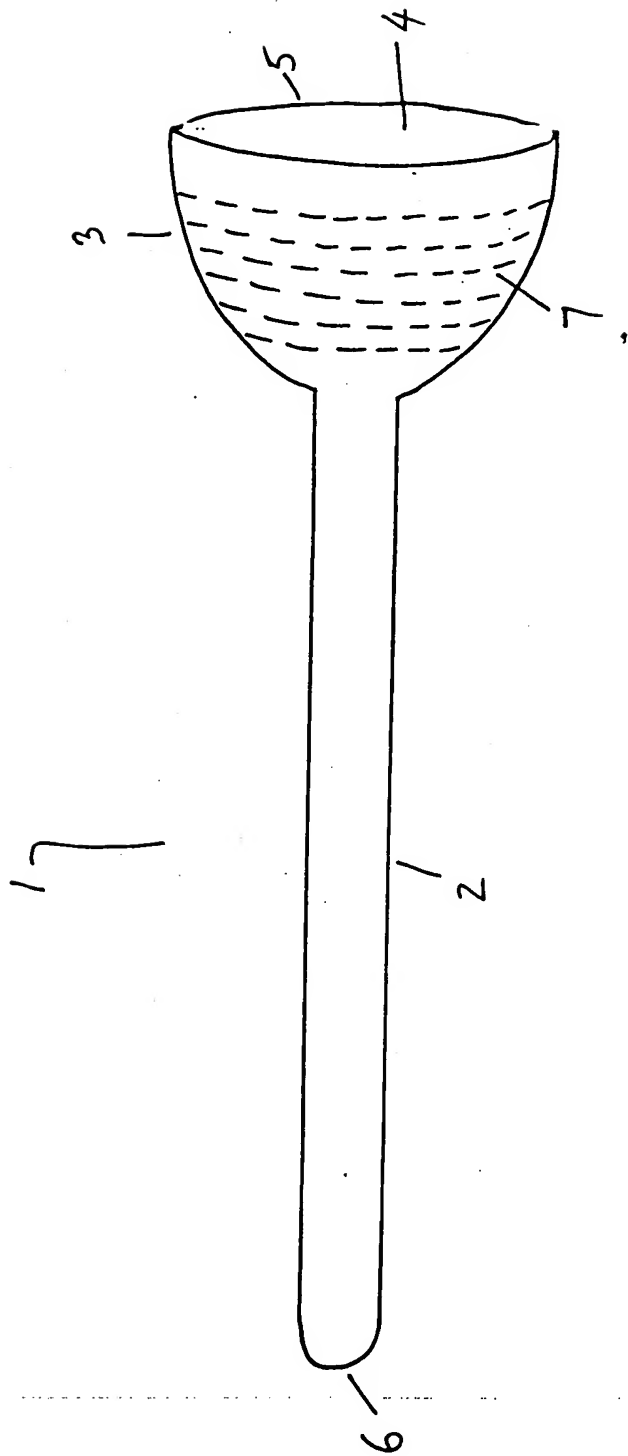


FIGURE 1.

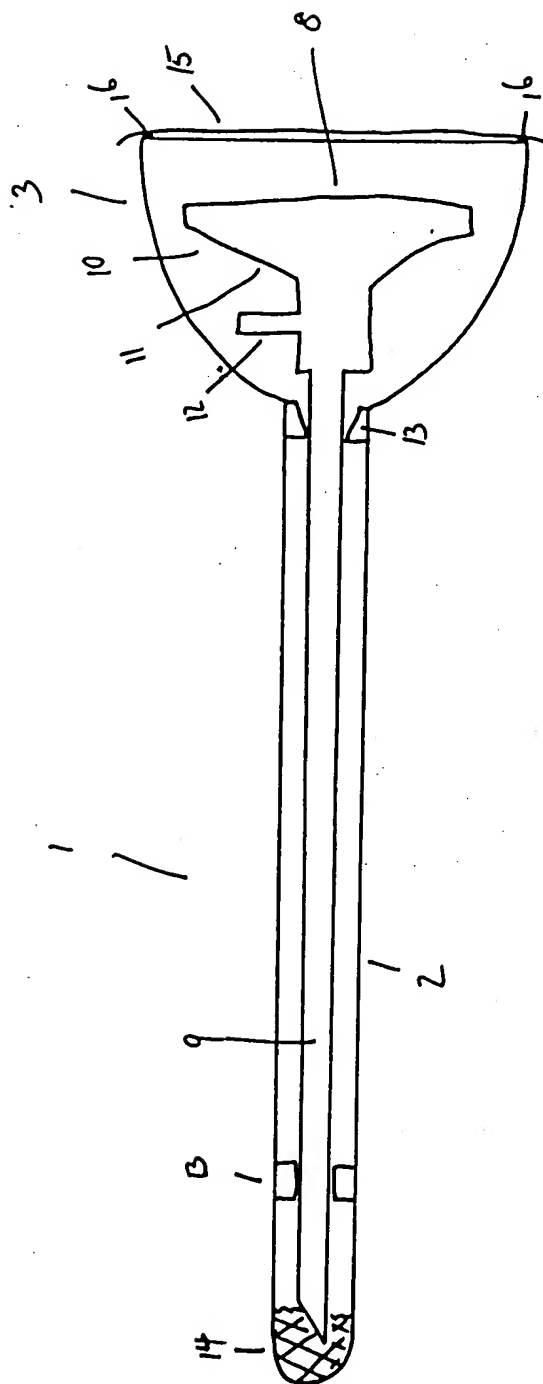


FIGURE 2

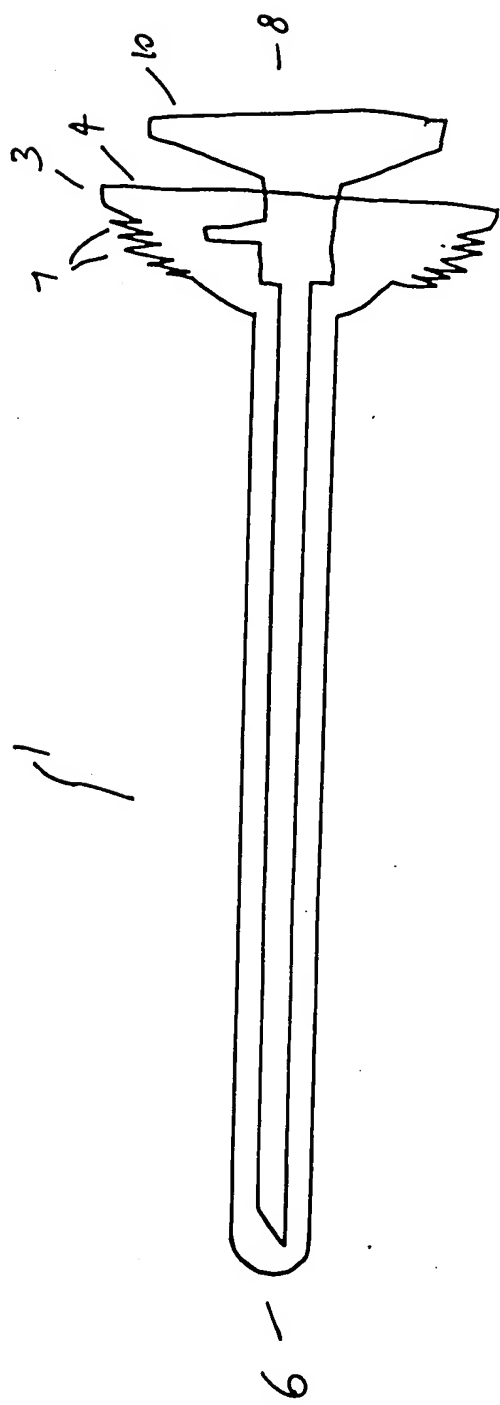


FIGURE 3

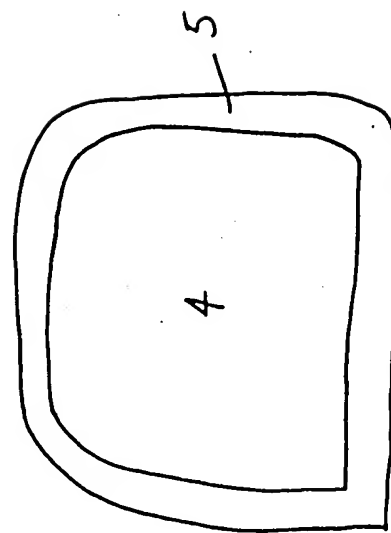


FIGURE 4



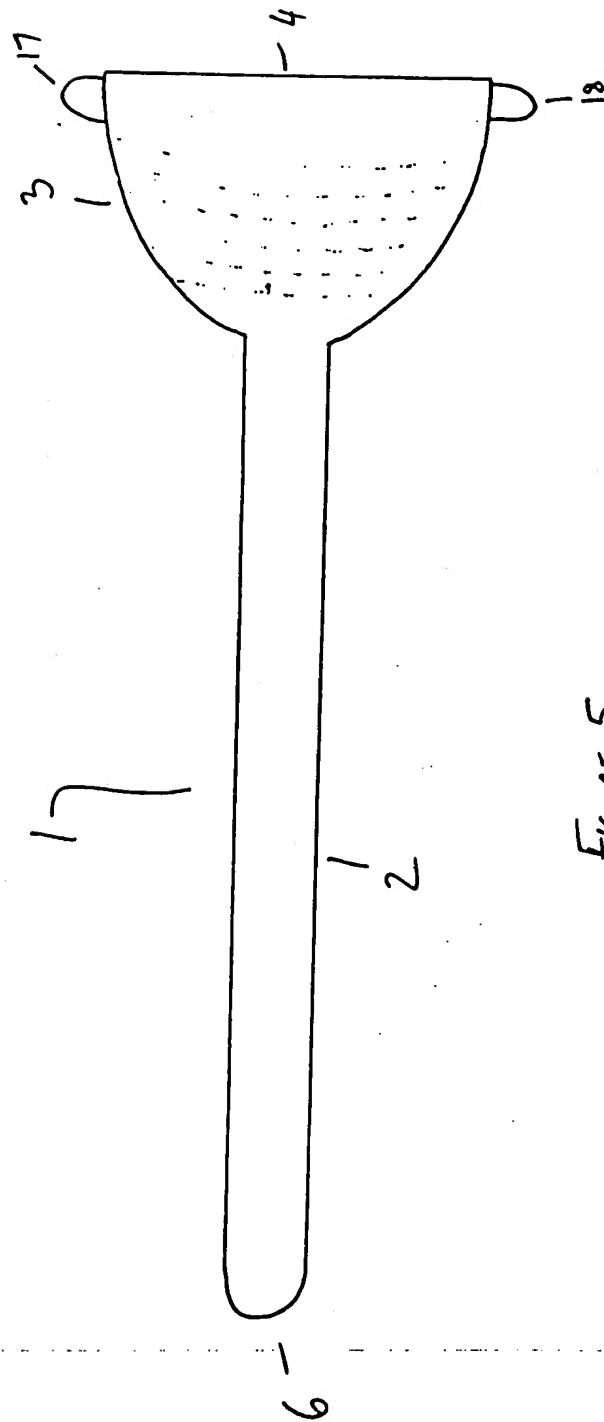


FIGURE 5

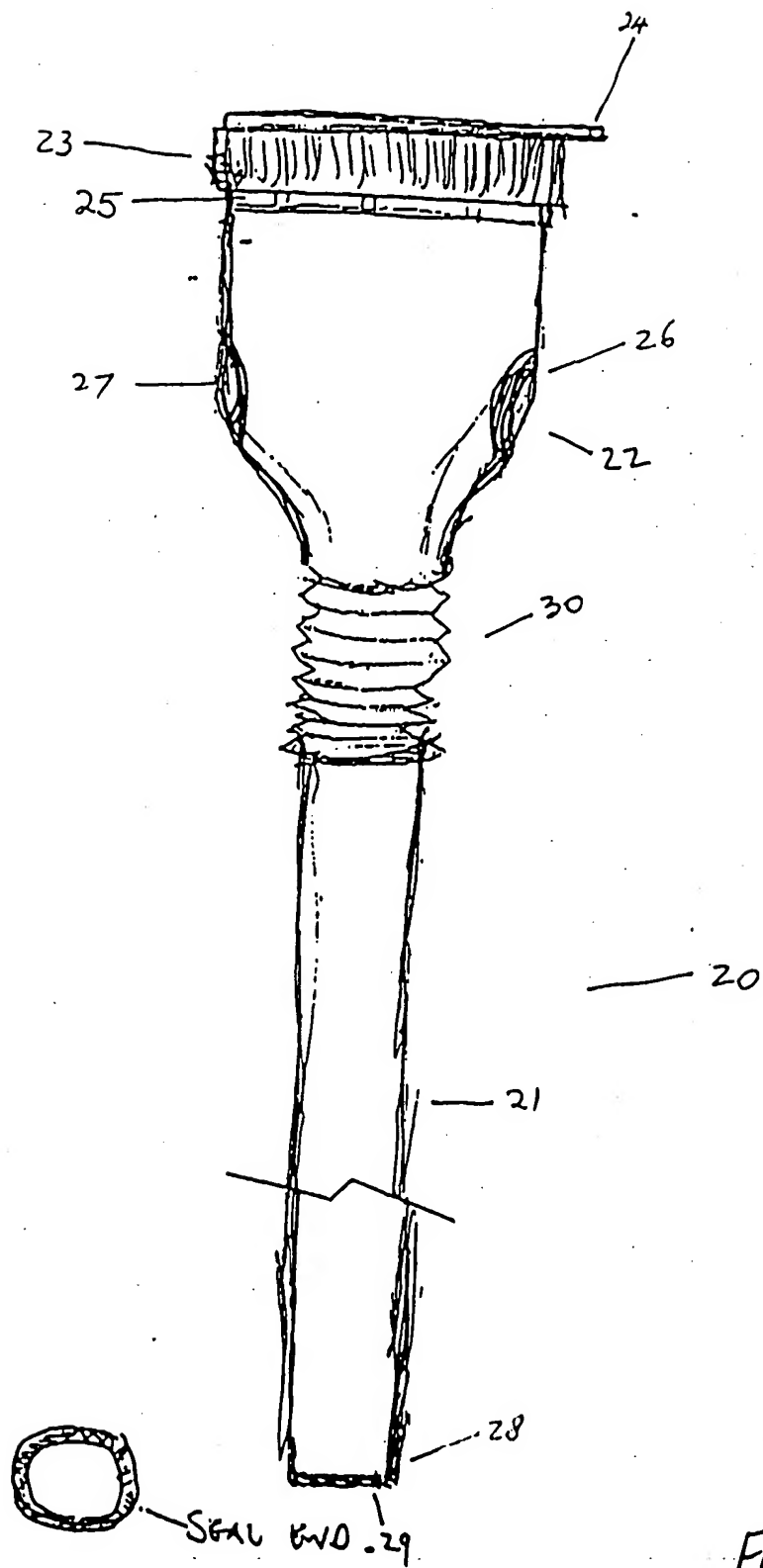


FIGURE 6.